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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/109,864 07/06/98 NI

J PF354P1

EXAMINER

022195 HM22/1012
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

ULM, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

22

10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/109,864

Applicant(s)
Ni et al.

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 30, 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-41, 43-93, 95, 106-110, 112-125, and 127-157 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-41, 43-93, 95, 106-110, 112-125, and 127-157 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18 20) ☐ Other:

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1) Claims 29 to 41, 43 to 93, 95, 106 to 110, 112 to 125 and 127 to 157 are pending in the instant application. Claims 44 and 73 have been amended, claims 111 and 126 have been canceled and claims 154 to 157 have been added as requested by Applicant in Paper Number 17, filed 30 March of 2001.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claim 44 is objected to as reciting an improper Markush Group for those reasons of record in section 5 of Paper Number 15. As stated therein, "unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility". To be more precise, unity of invention between a group of compounds exists where every member of that group has a common structural feature which serves as a basis for a common utility within the context of the claimed invention. Applicant urges that all of the compounds recited in the Markush Group share the common structural feature of being polynucleotides and that they have a common utility because each of them can be used to detect a polynucleotide encoding SEQ ID NO:2 in a sample. This argument is not persuasive because the common structural feature does not serve as a basis for the common utility. The vast majority of compounds which are polynucleotides can not be used to detect a polynucleotide encoding SEQ ID NO:2 in a sample. The polynucleotides recited

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in the Markush Group of this claim do not share a common structural feature which serves as a basis for a common utility and which distinguishes them as a group from other polynucleotides. Correction is required.

5) Claims 154 to 157 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. Each of these claims can be readily infringed by an isolated nucleic acid molecule which does not infringe claim 44, from which they depend.

6) Claims 29 to 41, 43 to 93, 95, 106 to 110, 112 to 125 and 127 to 157 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 29 to 41, 43 to 93, 95 and 105 to 153 in section 7 of Paper Number 15.

Applicant has traversed this rejection on the premise that the polypeptides of the instant invention are useful "as a cancer diagnostic and/or therapeutic". This assertion is not credible because it is unsupported by either evidence of the involvement of a protein of the instant invention in any particular oncogenic process or scientific reasoning which would support such a conclusion. At best, Applicant has shown that the overexpresion of the "galectin 11"protein in a host cell is toxic to that cell because it induces apoptosis. It is well known in the art that a

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number of receptors containing "death domains" induce apoptosis in a cell when either activated by a ligand or overexpressed. It is possible that a failure of apoptotic mechanisms may be involved in the proliferation of certain types of cancers. However, there is no evidence of record which supports a conclusion that the galectin 11 polypeptide of the instant invention is differentially expressed in any cancer. Therefore, to employ the claimed polynucleotides in the diagnosis of a cancer would require an artisan to first engage in the undue experimentation and inventive contribution of discovering the identity of a cancer in which galactin 11 is differentially expressed at a statistically significant level. Because the instant specification provides no evidence that galactin 11 is differentially expressed in a cancer then that artisan would not have a reasonable expectation of successfully identifying such a cancer.

Applicant's reliance on *In re Brana*, 51 F.3d 1560,1566, 34 USPQ2d 1436 ,1441 (Fed. Cir. 1995) is misplaced. That court decision determined that a compound which belonged to a family of compounds known to have anti-tumor activity, which is a common and well established specific and substantial utility for that family of compounds, would be reasonably expected to have anti-tumor activity in light of positive *in vitro* data with respect to that particular compound since that data has proven to be an indicator of anti-cancer activity by other members of that family. The protein of the instant invention does not belong to a family of compounds with a common well established specific and substantial utility. The utility of those members of the receptor family to which the claimed protein in the instant application belongs lies in the knowledge that they modulate a specific physiological activity in response to a specific ligand.

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Since the instant specification does not disclose the identity of a native ligand for the claimed protein or the identity of a disease or disorder with which the differential expression of that protein has been credibly associated, it lacks substantial and specific utility in currently available form.

7) Claims 29 to 41, 43 to 93, 95, 106 to 110, 112 to 125 and 127 to 157 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

8) Claims 136, 145 and 154 to 157 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claims 136 and 145 are vague and indefinite because there is no antecedent basis for "a polypeptide encoded by". The term "amino acid sequence" in claim 121 does not serve as a proper antecedent basis for "a polypeptide encoded by" in these claims.

8.2) Claims 154 to 157 are vague and indefinite because there is no antecedent basis for "the polynucleotide sequence of claim 44". Claim 44 is directed to "an isolated nucleic acid molecule".

9) Applicant's arguments filed 30 March of 2001 have been fully considered but they are not persuasive for those reasons given above.

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10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800